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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,872	06/29/1998	SYDNEY M PUGH	3477/116	6664

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/029,872
Filing Date: June 29, 1998
Appellant(s): PUGH ET AL.

MAILED

APR 06 2005

Group 3700

J. Scott Young
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 9, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

A copy of the present claims has been attached to this Examiner's Answer because a new set of claims was filed between the Appeal Brief dated October 28, 2003 and the Supplemental Appeal Brief filed July 9, 2004. The latest claims were not attached to the Supplemental Appeal Brief.

(4) *Status of Amendments After Final*

The Appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The Appellants' statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 33, 13, 22, 27, 29, 35, and 37, respectively, do not stand or fall together (with the rejections that they are under) and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

A copy of the appealed claims are attached as an appendix to this Answer because the claims were amended between the Appeal Brief dated October 28, 2003 and the Supplemental Appeal Brief filed July 9, 2004. The latest claims were not attached to the Supplemental Appeal Brief.

(9) Prior Art of Record

Ruys, A. J., "Silicon-Doped Hydroxyapatite", J. Aust. Ceram. Soc. 29 [1/2], (1993), pp 71-80.

WO94/26872	DAVIES	11-1994
4,983,182	KIJIMA et al	01-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34, and 38 are rejected under 35 U.S.C. 102(b)* as being anticipated by Ruys (article entitled "Silicone-doped Hydroxyapatite"). Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxylapatite and silicone which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). The result of Ruys' process is a bulk material. Furthermore, since the material of Ruys is the same as that claimed, it would inherently have the same resorbability and *in vivo* response as claimed; see page 72.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

With regard to claim 2, the higher concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 25, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same structural properties of Figure 14 as claimed. It is noted that Figure 14 is of very poor quality such that details thereof are not readily discernable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) alone.

With regard to claim 10, Ruys uses tetraethyl orthosilicate instead of tetrapropyl orthosilicate as claimed. However, since tetraethyl orthosilicate and tetrapropyl orthosilicate are homologues of each other, one would expect them to be quite similar in their function and perform quite similarly in the claimed invention. For this reason, it is the Examiner's position that it would have been prima facie obvious to substitute tetrapropyl orthosilicate for tetraethyl silicate in the Ruys invention because of the quite similar structure and function.

With regard to claim 26, Ruys fails to disclose the particle size as claimed even though it was disclosed as being crushed and pelletized; see page 76. However, since it was known, in the art, to crush and pelletize the same material as claimed, it is the Examiner's position that the mere selection of a particle size would have been considered prima facie obvious to an ordinary artisan because it has not shown to provide some advantage, solve some stated problem or used for some particular purpose, the Examiner takes the position that it would have

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been considered prima facie obvious to use the claimed particle size with the

Ruys composition; see MPEP 2144.04.

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 27, 29, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Davies (WO 94/26872). Ruys meets the claim language except for the presence of bone cells or their excreted materials, but Ruys envisions the need to assess the material for bone cell activity via clinical trials; see page 79. Davies teaches that it was known to assess bone cell activity by culturing bone cells on a support coated with a thin film of a sol-gel; see the abstract, page 1, lines 4-9, and column 4, lines 21-28, especially lines 21-25. Therefore, it would have been prima facie obvious to assess the bone cell activity of the Ruys composition, as taught by Davies, in order to see how effective it is as a bone growth or ingrowth promoter which was the desire of Ruys; see page 79 of Ruys under the heading "Conclusions."

With regard to claims 27 and 29, the Examiner posits that the claimed matrix would inherently be formed in the Davies modified Ruys device due to the same device being exposed to the same cells for a sufficient time for such matrix to form; see page 11, lines 17-31 of Davies.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Kijima et al (US 4,983,182). Ruys meets the claim language as set forth in the claim 1 rejection above but fails to disclose a coated form of the composition as claimed. However, Kijima teaches that it was known put similar tricalcium phosphate coatings on implants in order to make the surface biologically active such that bonding of the implant to the patient is improved; see the abstract and column 1, lines 5-27. Therefore, it is the Examiner's position that it would have been prima facie obvious to use the Ruys material as a coating for an implant in order to make the implant more bioactive as taught by Kijima.

(11) Response to Argument

Issue 1

Beginning on page 6 of the Brief, the Appellants argue that "the stabilized insoluble nature of the tricalcium phosphate" is different from that of Ruys' material. However, the Examiner asserts that since Ruys discloses making the same material in the same way as Appellants that it inherently or necessarily must have the same properties.

Appellants go on to argue that they "were the first to discover that the presence of stabilized entities can stabilize the composition and prevent its degradation in physiological fluids." However, the Examiner counters that the discovery of a new property does not render an otherwise old composition patentable; see MPEP 2112 (I), which is incorporated herein by reference. Appellants have provided no evidence that would suggest that their composition is any different from that disclosed by Ruys.

On page 8, first full paragraph of the Brief filed October 28, 2003, Appellants argue that “soluble” and “biodegradable” are synonymous even though claim 1 (line 5) requires that the stabilized tricalcium phosphate be resorbable. It seems clear to the Examiner that the Appellants are confusing insolubility with biodegradability. “Soluble” is denoted as “*capable of mixing with a liquid (dissolving) to form a homogeneous mixture (solution)*”; Hackh’s Chemical Dictionary, Fourth Edition, (1969), p. 624. “Biodegradable”, on the other hand, is denoted as “*Describing a substance that can be decomposed by biological action*”; see Hackh’s *supra*, p. 97. Therefore, to be “soluble” the molecules of a material merely need to physically separate into the solvent. However, biodegradability requires the material to be decomposed or chemically broken down to separate portions thereof from the whole by the actions of a biological organism or enzyme. For this reason, biodegradability is synonymous with resorbability by biological action.

Furthermore, claim 1 requires that the stabilized tricalcium phosphate is resorbable by osteoclasts, i.e. by biological action of the bone cells. Similarly, Ruys prefers low dopant levels to keep tricalcium phosphate “to a minimum and so eliminate the possibility of biodegradability *in vivo*”; see page 79, “Conclusions” section. For this reason, it is clear that Ruys also discloses that the tricalcium phosphate is resorbable or biodegradable and not soluble as defined by Hackh’s. Therefore, the Examiner asserts that Ruys discloses an insoluble TCP to the extent that such language can be given patentable weight.

Additionally, Appellants argue that insoluble tricalcium phosphate or stabilized tricalcium phosphate as claimed is different than soluble tricalcium phosphate; see page 7, first paragraph of the Appeal Brief filed October 28, 2003. However, the Examiner asserts that the term "insoluble" does not mean "degradation in physiological fluids" as argued (the paragraph bridging pages 7 and 8 in the Brief); i.e. this argument is not commensurate with the scope of the present claims. Furthermore, claim 1 states that the "stabilized tricalcium phosphate is resorbable by osteoclasts" (see lines 5-6 of claim 1). Not that this limitation is needed to meet the claim language, but Ruys discloses a range of silicone, which avoids forming biodegradable TCP (tricalcium phosphate); see the last paragraph on page 71. For this reason, the insoluble tricalcium phosphate called for in claim 1 is fully met by Ruys even when the term "insoluble" is interpreted to mean non-resorbable or non-biodegradable.

Although Appellants have had several opportunities to do so, Appellants have never provided evidence of this alleged difference between the Ruys material and the material of the presently claimed invention. MPEP 2112 is incorporated herein by reference as follows:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596

(CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Issue 2

Appellants argue that there is no motivation to modify Ruys to arrive at the presently claimed invention. However, the Examiner asserts that the difference between Ruys and the claimed invention is so slight that it would have been *prima facie* obvious to make the modification suggested. Since Appellants have provided no reason why such a modification was made, the Examiner asserts that it is *prima facie* obvious to do so.

The other argument raised with respect to this issue has already been addressed in the Issue 1 section *supra*.

Issue 3

Appellants argue that Ruys teaches away from the claimed invention because it prefers low dopant levels. However, the Examiner asserts that Ruys makes a wide range of silicon-doped materials for testing purposes. However, Ruys suggests that lower dopant levels would be better to avoid biodegradability. This is the same reason that Appellants want an insoluble stabilized material, that is, to form a stable implant material as a scaffold or lattice for new bone growth. For this reason, the Examiner asserts that both the Appellants and Ruys are teaching the same thing, but have merely explained it in a different way.

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Next, Appellants argue that Ruys does not test the material in any manner so he cannot suggest the use of its material as an implant. However, it is clear that Ruys suggests that this should be done; see the "Conclusions" section. This is all that is needed to form a nexus with Davies. Furthermore, upon reading Appellants disclosure, it was noted that there is no evidence that Appellants ever tested their material in any manner as an implant.

Issue 4

Appellant merely argue that Kijima fails to cure what they see as the deficiencies of Ruys. However, Kijima was not applied to demonstrate the obviousness of the argued features, and thus, these arguments are not relevant to the rejection as it is set forth. Since Ruys does disclose every limitation of claim 1, as explained above, Appellant's arguments are considered unpersuasive. Furthermore, to argue that the secondary reference does not have features that it is not said to teach is not relevant or persuasive with respect to the rejection.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

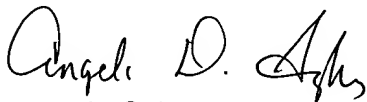


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